Methods

Monitoring progress in TB control (1995–2005)

Goals, targets and indicators for TB control

The target and indicators for TB control, defined within the framework of the MDGs, have been supplemented and endorsed by the Stop TB Partnership (Table 1).[1] These will be used to measure progress made under the Stop TB Strategy,[2] which extends and enhances the DOTS strategy (Tables 2, 3). The Global Plan to Stop TB[3] describes how the Stop TB Strategy should be implemented over the decade 2006–2015.

This report focuses on the five principal indicators that are used to measure the implementation and impact of TB control: case detection and treatment success, and incidence, prevalence and deaths. The objective of reducing incidence is made explicit by MDG Target 8; the targets of 70% case detection and 85% treatment success were set by WHO's World Health Assembly;[4] the targets for prevalence and deaths are based on a resolution of the year 2000 meeting of the Group of Eight (G8) industrialized countries, held in Okinawa, Japan. The targets for case detection and treatment success should have been reached by the end of 2005. This report presents the best possible assessment, based on case reports to the end of 2005, of whether the targets were reached in the world as a whole, and in each WHO region and country.

Data collection and verification

Every year, WHO requests information from NTPs or relevant public health authorities in 212 countries or territories[5] via a standard data collection form.[6] The latest form was distributed in mid-2006. The section dealing with monitoring and surveillance asked for data including the following: whether the elements of DOTS and the Stop TB Strategy were being implemented during 2005; DOTS population coverage in 2005; TB case notifications in 2005 (from DOTS and non-DOTS areas, each with 12 categories; new pulmonary smear-positive cases by age and sex); TB patients tested for HIV and MDR-TB in 2005; and treatment outcomes for TB patients registered during 2004 (DOTS, non-DOTS, HIV-infected, each with 7 categories) and MDR-TB patients registered during 2002

TABLE 1

Goals, targets and indicators for TB control

MILLENNIUM DEVELOPMENT GOAL 6

Combat HIV/AIDS, malaria and other diseases

Target 8:	Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases
Indicator 23:	Prevalence and death rates associated with tuberculosis
Indicator 24:	Proportion of tuberculosis cases detected and cured under DOTS (the internationally recommended strategy for TB control)

STOP TB PARTNERSHIP TARGETS

By 2005:	At least 70% of people with sputum smear-positive TB will be diagnosed (i.e. under the DOTS strategy), and at least 85% cured. These are targets set by the World Health Assembly of WHO.
By 2015:	The global burden of TB (per capita prevalence and death rates) will be reduced by 50% relative to 1990 levels.
By 2050:	The global incidence of active TB will be less than 1 case per million population per year.

TABLE 2

Components of the Stop TB Strategy

1. **Pursuing high-quality DOTS expansion and enhancement**
   a. Political commitment with increased and sustained financing
   b. Case detection through quality-assured bacteriology
   c. Standardized treatment with supervision and patient support
   d. An effective drug supply and management system
   e. Monitoring and evaluation system, and impact measurement
2. **Addressing TB/HIV, MDR-TB and other challenges**
   — Implement collaborative TB/HIV activities
   — Prevent and control MDR-TB
   — Address prisoners, refugees, other high-risk groups and special situations
3. **Contributing to health system strengthening**
   — Actively participate in efforts to improve system-wide policy, human resources, financing, management, service delivery and information systems
   — Share innovations that strengthen health systems, including the Practical Approach to Lung Health (PAL)
   — Adapt innovations from other fields
4. **Engaging all care providers**
   — Public–Public and Public–Private Mix (PPM) approaches
   — Implement International Standards for Tuberculosis Care
5. **Empowering people with TB, and communities**
   — Advocacy, communication and social mobilization
   — Community participation in TB care
   — Patients' Charter for Tuberculosis Care
6. **Enabling and promoting research**
   — Programme-based operational research
   — Research to develop new diagnostics, drugs and vaccines

[1] Dye C et al. Targets for global tuberculosis control. *International Journal of Tuberculosis and Lung Disease*, 2006, 10:460–462.

[2] Raviglione MC, Uplekar MW. WHO's new Stop TB Strategy. *Lancet*, 2006, 367:952–955.

[3] *The Global Plan to Stop TB, 2006–2015*. Geneva, Stop TB Partnership and World Health Organization, 2006 (WHO/HTM/STB/2006.35).

[4] Resolution WHA44.8. Tuberculosis control programme. In: *Handbook of resolutions and decisions of the World Health Assembly and the Executive Board*. Volume III, 3rd ed. (1985–1992). Geneva, World Health Organization, 1993 (WHA44/1991/REC/1).

[5] Serbia and Montenegro were treated as separate countries from 2005 onwards, increasing the 2004 total by one.

[6] Posted at www.who.int/tb/country/en/

TABLE 3

Technical elements of the DOTS strategy

Case detection through quality-assured bacteriology Case detection among symptomatic patients self-reporting to health services, using sputum smear microscopy. Sputum culture is also used for diagnosis in some countries, but direct sputum smear microscopy should still be performed for all suspected cases.
Standardized treatment with supervision and patient support Standardized short-course chemotherapy using regimens of 6–8 months for at least all confirmed smear-positive cases. Good case management includes directly observed treatment (DOT) during the intensive phase for all new smear-positive cases, during the continuation phase of regimens containing rifampicin and during the entirety of a re-treatment regimen. In countries that have consistently documented high rates of treatment success, DOT may be reserved for a subset of patients, as long as cohort analysis of treatment results is provided to document the outcome of all cases.
An effective drug supply and management system Establishment and maintenance of a system to supply all essential anti-TB drugs and to ensure no interruption in their availability.
Monitoring and evaluation system, and impact measurement Establishment and maintenance of a standardized recording and reporting system, allowing assessment of treatment results (see Tables 4, 5).

(GLC-approved and other, each with 3 categories). The main case definitions are given in Table 5.

The data collection form used in the WHO European Region asked for additional data, including a breakdown of all TB cases by age, geographical origin (e.g. born outside country/non-citizen) and mycobacterial culture result; all TB cases by HIV serostatus and age; and HIV-positive TB cases by sex and age. For NTPs in the 63 countries that account for 98% of all HIV-infected TB patients, the data collection form was extended to obtain further information about TB linked to HIV infection (see **Collaborative TB/HIV activities**).

As NTPs respond to WHO, they are also asked to update information for earlier years if they are able to do so. As a result of such revisions, the data (case notifications, treatment outcomes, etc.) presented in this report for years preceding 2004 and 2005 may differ from those published in previous reports.

The standard data collection form is used to compile aggregated national data. The process of national and international reporting is distinct from WHO's recommendations about procedures for recording and reporting data by NTPs within countries, from district level upwards.[1]

Completed forms are collected and reviewed at all levels of WHO, by country offices, regional offices and at headquarters. An acknowledgement form that tabulates all submitted data is sent back to the NTP correspondent in order to complete any missing responses and to resolve any inconsistencies. Then, using the complete set of data for each country, we construct a profile that tabulates all key indicators, including epidemiological and financial data and estimates, and this too is returned to each NTP for review. In the WHO European Region only, data collection and verification are performed jointly by the regional office and a WHO collaborating centre, EuroTB (Paris). EuroTB subsequently publishes an annual report with additional analyses, using more detailed data for the European Region (www.eurotb.org).

High-burden countries, WHO regions and other subregions of the world

Much of the data submitted to WHO is shown, country by country, in the annexes of this report. The analysis and interpretation that precede these annexes focus on 22 HBCs and the six WHO regions. The 22 HBCs account for approximately 80% of the estimated number of new TB cases (all forms) arising worldwide each year. These countries are the focus of intensified efforts in DOTS expansion (Annex 1). The HBCs are not necessarily those with the highest incidence rates per capita; many of the latter are medium-sized African countries with high rates of TB/HIV coinfection. The WHO regions are the African Region, the Region of the Americas, the Eastern Mediterranean Region, the European Region, the South-East Asia Region and the Western Pacific Region. All essential statistics are summarized for each of these regions and globally. However, to make clear the differences in epidemiological trends within regions, we divide the African Region into countries with low and high rates of HIV infection ("high" is an infection rate of ≥4% in adults aged 15–49 years, as estimated by UNAIDS in 2004). We also distinguish central from eastern Europe (countries of the former Soviet Union plus Bulgaria and Romania), and combine western European countries with the other established market economies. The countries within each of the resulting nine subregions are listed in the legend to Figure 5.

Implementation of DOTS and the Stop TB Strategy

DOTS remains central to the public health approach to TB control, which is now presented as the Stop TB Strategy (Table 2). Before the launch of the strategy during 2006, NTPs reporting to WHO were classified as either DOTS or non-DOTS, based on the elements listed in Tables 2 and 3. To be classified as DOTS in this report, a country must have officially accepted and adopted the strategy in 2005, and must have implemented the four technical components of DOTS in at least part of the country (Annex 2). Based on NTP responses to standard questions about policy – and usually on further discussion with the NTP – we have accepted or revised each country's own determination of its DOTS status.

[1] Revised procedures for recording and reporting at district level are described at www.who.int/tb/publications/recording_and_reporting_draft/en/index.html

DOTS coverage

Coverage is defined as the percentage of the national population living in areas where health services have adopted DOTS. "Areas" are the lowest administrative or basic management units[1] in the country (townships, districts, counties, etc.). If an area (with its one or more health facilities) is considered by the NTP to have been a DOTS area in 2005, then all the cases registered and reported by the NTP in that area are considered DOTS cases, and the population living within the boundaries of that area counts towards the national DOTS coverage. In some cases, treatment providers that are not following DOTS guidelines (e.g. private practitioners, or public health services outside the NTP such as those within prisons) notify cases to the NTP. These cases are considered non-DOTS cases, even if they are notified from within DOTS areas. However, when certain groups of patients treated by DOTS services receive special regimens or management (e.g. nomads placed on longer courses of treatment), these are considered DOTS cases. Where possible, additional information about these special groups of patients is provided in the country notes in Annex 2. Ideally, the DOTS coverage in any one year should be calculated by evaluating the number of person-years covered in each quarter, and then summing across the four quarters of the year (although some countries simply report the population coverage achieved by the end of the year).

DOTS coverage calculated as described above is a crude indicator of the actual proportion of people who have access to DOTS services, but it is easy to calculate and is most useful during the early stages of DOTS expansion. As a measure of patient access to diagnosis and treatment under DOTS, coverage is an approximation, and usually an overestimate. Where countries are able to provide more precise information about access to DOTS services, this information is reported in the country notes of Annex 2. The case detection rate (defined below) is a more precise measure of DOTS implementation but is also more demanding of data.

Estimating TB incidence, prevalence and death rates

Estimates of TB incidence, prevalence and deaths are based on a consultative and analytical process. They are revised annually to reflect new information gathered through surveillance (case notifications and death registrations) and from special studies (including surveys of the prevalence of infection and disease). The details of estimation are described elsewhere.[2,3,4] In brief, estimates of incidence (number of new cases arising each year) for each country are derived using one or more of four approaches, depending on the available data:

$$\text{incidence} = \frac{\text{case notifications}}{\text{proportion of cases detected}} \quad (1)$$

$$\text{incidence} = \frac{\text{prevalence}}{\text{duration of condition}} \quad (2)$$

$$\text{incidence} = \text{annual risk of infection} \times \text{Stýblo coefficient} \quad (3)$$

$$\text{incidence} = \frac{\text{deaths}}{\text{proportion of incident cases who die}} \quad (4)$$

The Stýblo coefficient in equation (3) is taken to be a constant, with an empirically derived value in the range 40–60, relating risk of infection (% per year) to the incidence of sputum smear-positive cases (per 100 000 per year). Given two of the quantities in any of these equations, we can calculate the third, and these formulae can be rearranged to estimate incidence, prevalence and death rates. The available data differ from country to country, and not all methods can be applied in every country.

Among all new, HIV-negative TB patients, 45% are assumed to be smear-positive (ranging uniformly between 40% and 50% in uncertainty analysis). Among HIV-positive TB patients, the fraction is smaller (35%, range 30–40%). Because most NTPs still do not routinely test TB patients for HIV infection, we have used, for all countries, an indirect estimate of the prevalence of HIV among new TB patients, calculated from:

$$\text{prevalence of HIV in new TB patients} = \frac{p_{\text{HIV}} \times \text{IRR}}{1+p_{\text{HIV}}(\text{IRR}-1)} \quad (5)$$

where p_{HIV} is HIV prevalence in the adult population (15–49 years) and IRR is the incidence rate ratio, i.e. the TB incidence rate in HIV-infected adults divided by the TB incidence rate in HIV-uninfected adults. IRR takes values of 30 (range 21–39, with a triangular distribution in uncertainty analysis) for the established market economies and 6.0 (range 3.5–8.0) for all other countries.[5]

1 The basic management unit is defined in terms of management, supervision, and monitoring responsibility. It may have several treatment facilities, one or more laboratories, and one or more hospitals. The defining aspect is the presence of a manager or coordinator who oversees TB control activities for the unit and who maintains a master register of all TB patients being treated, which is used to monitor the programme and report on indicators to higher levels.

2 Dye C et al. Global burden of tuberculosis: estimated incidence, prevalence and mortality by country. *Journal of the American Medical Association*, 1999, 282:677–686.

3 Corbett EL et al. The growing burden of tuberculosis: global trends and interactions with the HIV epidemic. *Archives of Internal Medicine*, 2003, 163:1009–1021.

4 Dye C et al. Evolution of tuberculosis control and prospects for reducing tuberculosis incidence, prevalence, and deaths globally. *Journal of the American Medical Association*, 2005, 293:2767–2775.

5 Corbett EL et al. The growing burden of tuberculosis: global trends and interactions with the HIV epidemic. *Archives of Internal Medicine*, 2003, 163:1009–1021. The estimated IRR of 30 for the established market economies was reduced from the original estimate of 60 based on 2001 data published by the United States Centers for Disease Control and Prevention. The estimate of 6 for all other countries was reviewed with a new compilation of data, made in January 2007, from approximately 200 studies. The new analysis gave a point estimate of IRR close to 6, on which basis we retained the original estimate used by Corbett et al. Further details are available from tbdocs@who.int

For each country, estimates of incidence for each year during the period 1995–2005 were made as follows. We first selected a reference year for which we have a best estimate of incidence; this may be the year in which a survey was carried out, or the year for which incidence was first estimated. We then use the series of case notifications (all new and relapse cases) to determine how incidence changed before and after that reference year. The time series of estimated incidence rates is constructed from the notification series in one of two ways: if the rate of change of case notifications is roughly constant through time, we fitted exponential trends to the notification series (subregions Africa low-HIV, Latin America, South-East Asia, Western Pacific); if the rate varies through time (subregions Africa high-HIV, Central Europe, Eastern Europe, Eastern Mediterranean, Established Market Economies), we used a three-year moving average of the notification rates. If the notifications for any country are considered to be an unreliable guide to trend (e.g. because reporting effort is known to have changed; or because reports are clearly erratic, changing in a way that cannot be attributed to TB epidemiology), we applied the aggregated trend for all other countries from the same epidemiological region that have reliable data. For some countries, we used an assessment of the trend in incidence based on risk of infection derived from other sources (tuberculin surveys for China and Nepal). For those countries that have no reliable data from which to assess trends in incidence (e.g. for countries such as Iraq and Pakistan, for which data are hard to interpret, and which are atypical within their own regions), we assumed that incidence is stable.

Estimates of incidence form the denominator of the case detection rate. Trends in incidence are governed by underlying epidemiological processes, modified by control programmes. The impact of control on prevalence is determined by the trend in incidence and by the estimated reduction in the duration of the condition, e.g. smear-positive disease.

The prevalence of TB is calculated from the product of incidence and duration of disease (rearranging equation 2), and the TB mortality rate from the product of incidence and case fatality (proportion of incident cases who ever die from TB; equation 4). The duration of disease and the case fatality are estimated, country by country, for patients treated within or outside DOTS programmes and for patients who receive no recognized anti-TB treatment. Because the duration of disease and case fatality are typically shorter for patients treated under DOTS than for patients who are treated elsewhere or untreated, the average duration of disease and average case fatality decrease as the proportion of patients treated under DOTS increases.[1,2,3]

Where population sizes are needed to calculate TB indicators, we use the latest revision of estimates provided by the United Nations Population Division.[4] These estimates sometimes differ from those made by the countries themselves, some of which are based on more recent census data. The estimates of some TB indicators, such as the case detection rate, are derived from data and calculations that use only rates per capita, and discrepancies in population sizes do not affect these indicators. Where rates per capita are used as a basis for calculating numbers of TB cases, these discrepancies sometimes make a difference. Some examples of important differences are given in the country notes in Annex 2.

Because accurate measurement is crucial in the evaluation of epidemic trends, Table 4 provides some methodological guidance, based on a review by a WHO panel of experts in June 2006. Table 4 can be read in conjunction with the list of countries that have done, or are planning, infection (tuberculin) and disease prevalence surveys, and with the set of countries that now register deaths by cause and provide these data to WHO (including TB; Annex 3).

Case notification and case detection

Sputum smear-positive cases are the focus of DOTS programmes because they are the principal sources of infection to others, because sputum smear microscopy is a highly specific (if somewhat insensitive) method of diagnosis, and because patients with smear-positive disease typically suffer higher rates of morbidity and mortality than smear-negative patients. As a measure of the quality of diagnosis, we calculate the proportion of new smear-positive cases out of all new pulmonary cases, which has an expected value of at least 65% in areas with negligible HIV prevalence.[5]

The term "case notification", as used here, means that TB is diagnosed in a patient and is reported within the national surveillance system, and then to WHO. While the emphasis is on new smear-positive cases, we also present the numbers of all TB cases reported – smear-positive and smear-negative pulmonary cases – in addition to those in whom extrapulmonary disease is diagnosed. The number of cases notified in any year is the sum of new and relapse cases. Case reports that represent a second registration of the same patient/episode (i.e. re-treatment after failure or default) are presented separately.

The case detection rate is calculated as the number of cases notified divided by the number of cases estimated for that year, expressed as a percentage. Detection is presented in four main ways: (a) for new smear-positive cases

[1] Dye C et al. Global burden of tuberculosis: estimated incidence, prevalence and mortality by country. *Journal of the American Medical Association*, 1999, 282:677–686.

[2] Corbett EL et al. The growing burden of tuberculosis: global trends and interactions with the HIV epidemic. *Archives of Internal Medicine*, 2003, 163:1009–1021.

[3] Dye C et al. Evolution of tuberculosis control and prospects for reducing tuberculosis incidence, prevalence, and deaths globally. *Journal of the American Medical Association*, 2005, 293:2767–2775.

[4] *World population prospects – the 2002 revision*. New York, United Nations Population Division, 2003.

[5] *Tuberculosis handbook*. Geneva, World Health Organization, 1998 (WHO/TB/98.253).

TABLE 4

Methods to measure progress in TB control: recommendations of a WHO task force (June 2006)[a]

Routine TB surveillance and monitoring

- Routine surveillance (all reported cases) and monitoring (treatment outcomes) should be considered the ultimate method of evaluating TB epidemiology and control.
- All national TB control programmes (NTPs) should strengthen and evaluate the performance of systems for reporting TB cases so that the data reflect, to a close approximation, the true incidence of TB and its time trend. The process of evaluation should be supported by appropriate operational research studies.
- The analysis of disaggregated surveillance data should be encouraged (e.g. clinic, district, province; by age, sex, etc.) so as to draw out the maximum information on the TB epidemic and the impact of control measures.
- Appropriate computer software should be developed and implemented to improve routine recording and reporting.

Surveys of disease prevalence

- Countries with high and intermediate TB burdens are encouraged to carry out one or a series of disease prevalence surveys if these are likely to be beneficial in assessing prevalence and trends, and/or optimizing planning for TB control. The decision to carry out a prevalence survey in any country should be guided by criteria (to be further defined), which will include:
  - Poor information on burden and trends of TB disease
  - Functional TB control programme that can utilize survey results to guide implementation of control activities
  - High HIV burden
  - Weak or poorly informative surveillance system
  - Available experience and expertise (national and/or international)
  - Willingness of the NTP to support national prevalence surveys
  - Full participation of population to be surveyed
  - Logistic feasibility and security for field staff

Surveys of infection prevalence

- Acknowledging the importance of measuring infection, but understanding the limitations of the tuberculin technique, tuberculin skin test surveys (TSTs) are recommended only in settings where they are likely to be informative about the prevalence and risk of infection and its trend. A TST is not guaranteed to give interpretable results in any setting, but is more likely to be useful for measuring trends, and where there is:
  - data on infection prevalence from previous surveys
  - a firm plan to repeat surveys
  - a high risk of infection
  - capacity to ensure strict adherence to standardized methodology
- In view of the evidence provided by tuberculin surveys conducted in the past decade, it is no longer generally advisable to estimate the incidence of TB (smear-positive cases) from the annual risk of infection by applying the Styblo rule (incidence of ss+ TB increases by 50/100 000 population for every 1% increase in annual risk of infection). However, the rule appears still to apply in some countries, notably India, and WHO estimates for some countries have, in the absence of better information, been derived by this method.

Evaluating TB mortality

- The accuracy of the current cohort monitoring system in correctly capturing deaths among TB patients should be reviewed and optimized.
- The study of TB mortality in the general population (i.e. outside treatment cohorts) should be undertaken in the context of studies of all causes of death.
  - Vital registration. NTPs should ensure linkages and cross-referencing of data from cohort monitoring with data from available and developing death registration systems, thereby improving vital statistics.
  - Verbal autopsy. Further evaluations are needed to establish the reliability and validity of verbal autopsies as a way of evaluating TB deaths in the general population, and their feasibility within general cause-of-death surveys.

[a] The full set of recommendations is available at www.who.int/tb/country/en/

(excluding relapses); (b) for all new cases (all clinical forms of TB, excluding relapses); (c) for DOTS programmes only; or (d) for cases notified from all sources (DOTS and non-DOTS areas). For new smear-positive cases aggregated as in (c) and (d):

$$\text{DOTS case detection rate} = \frac{\text{annual new smear-positive notifications (DOTS)}}{\text{estimated annual new smear-positive incidence (country)}} \quad (6)$$

$$\text{Case detection rate} = \frac{\text{annual new smear-positive notifications (country)}}{\text{estimated annual new smear-positive incidence (country)}} \quad (7)$$

The target of 70% case detection applies to the DOTS case detection rate in formula (6). Even when a country is not 100% DOTS, we use the incidence estimated for the whole country as the denominator of the case detection rate, as in equation (6). The DOTS detection rate and the case detection rate for the whole country are identical when a country reports only from DOTS areas. This generally happens when DOTS coverage is 100%, but in some countries where DOTS is implemented in only part of the country, no TB notifications are received from the non-DOTS areas. Furthermore, in some countries where DOTS coverage is 100%, patients may seek treatment from non-DOTS providers that, in some cases, notify TB cases to the national authorities.

Although these indices are termed "rates", they are actually ratios. The number of cases notified is usually smaller than the estimated incidence because of incomplete coverage by health services, under-diagnosis, or deficient recording and reporting. However, the calculated detection rate can exceed 100% if case-finding has been intense in an area that has a backlog of existing cases, if there has been over-reporting (e.g. double-counting) or over-diagnosis, or if estimates of incidence are too low. If the expected number of cases per year is very low (e.g. less than one), the case detection rate can vary markedly from year to year because of chance. Whenever this index comes close to or exceeds 100%, we attempt to investigate, as part of the joint planning and evaluation process with NTPs, which of these explanations is correct.

The ratio of the DOTS case detection rate to coverage is an estimate of the case detection rate within DOTS areas (as distinct from the case detection rate nationwide), assuming that the TB incidence rate is homogeneous across counties, districts, provinces or other administrative units. The detection rate within DOTS areas should exceed 70% as DOTS coverage increases within any country. The value of this indicator is low when the DOTS programme has been poorly imple-

mented, when access to DOTS is limited, or when TB incidence in DOTS areas has been overestimated. Changes in the value of this ratio through time are a measure of changes in the quality of TB control, after the DOTS programme has been established.

Outcomes of treatment

Treatment success in DOTS programmes is the percentage of new smear-positive patients who are cured (negative on sputum smear examination), plus the percentage who complete a course of treatment, without bacteriological confirmation of cure (Table 5). Cure and completion are among the six mutually exclusive treatment outcomes.[1] The sum of cases assigned to these outcomes, plus any additional cases registered but not assigned to an outcome, adds up to 100% of cases registered (i.e. the treatment cohort).

We also compare the number of new smear-positive cases registered for treatment (for this report, in 2004) with the number of cases notified as smear-positive (also in 2004). All notified cases should be registered for treatment, and the numbers notified and registered should therefore be the same (discrepancies arise, for example, when subnational reports are not received at national level). If the number registered for treatment is not provided, we take as the denominator for treatment outcomes the number notified for that cohort year. If the sum of the six outcome categories is greater than the number registered (or the number notified), we use this sum as the denominator.

The number of patients presenting for a second or subsequent course of treatment, and the outcome of further treatment, are indicative of NTP performance and levels of drug resistance. We present in this report, where data are available, the numbers of patients registered for re-treatment, and the outcomes of re-treatment, for each of four registration categories: smear-positive re-treatment after relapse; failure; default; and other re-treatment (including pulmonary smear-negative and extrapulmonary).

The assessment of treatment outcomes for a given calendar year always lags case notifications by one year, to ensure that all patients registered during that calendar year have completed treatment. For MDR-TB patients, who have longer treatment regimens, the lag is three years. A DOTS country must report treatment outcomes, unless

[1] *Treatment of tuberculosis: guidelines for national programmes*. 3rd ed. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.313).

TABLE 5

Definitions of tuberculosis cases and treatment outcomes

A. DEFINITIONS OF TUBERCULOSIS CASES

CASE OF TUBERCULOSIS A patient in whom tuberculosis has been confirmed by bacteriology or diagnosed by a clinician.

DEFINITE CASE A patient with positive culture for the *Mycobacterium tuberculosis* complex. In countries where culture is not routinely available, a patient with two sputum smears positive for acid-fast bacilli (AFB+) is also considered a definite case.

PULMONARY CASE A patient with tuberculosis disease involving the lung parenchyma.

SMEAR-POSITIVE PULMONARY CASE A patient with at least two initial sputum smear examinations (direct smear microscopy) AFB+; or one sputum examination AFB+ and radiographic abnormalities consistent with active pulmonary tuberculosis as determined by a clinician; or one sputum specimen AFB+ and culture positive for *M. tuberculosis*.

SMEAR-NEGATIVE PULMONARY CASE A patient with pulmonary tuberculosis not meeting the above criteria for smear-positive disease. Diagnostic criteria should include: at least three sputum smear examinations negative for AFB; and radiographic abnormalities consistent with active pulmonary tuberculosis; and no response to a course of broad-spectrum antibiotics; and a decision by a clinician to treat with a full course of antituberculosis chemotherapy; or positive culture but negative AFB sputum examinations.

EXTRAPULMONARY CASE A patient with tuberculosis of organs other than the lungs (e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges). Diagnosis should be based on one culture-positive specimen, or histological or strong clinical evidence consistent with active extrapulmonary disease, followed by a decision by a clinician to treat with a full course of antituberculosis chemotherapy. A patient in whom both pulmonary and extrapulmonary tuberculosis has been diagnosed should be classified as a pulmonary case.

NEW CASE A patient who has never had treatment for tuberculosis or who has taken antituberculosis drugs for less than one month.

RELAPSE CASE A patient previously declared cured but with a new episode of bacteriologically positive (sputum smear or culture) tuberculosis.

RE-TREATMENT CASE A patient previously treated for tuberculosis, undergoing treatment for a new episode, usually of bacteriologically-positive tuberculosis.

B. DEFINITIONS OF TREATMENT OUTCOMES

(expressed as a percentage of the number registered in the cohort)

CURED A patient who was initially smear-positive and who was smear-negative in the last month of treatment and on at least one previous occasion.

COMPLETED TREATMENT A patient who completed treatment but did not meet the criteria for cure or failure. This definition applies to pulmonary smear-positive and smear-negative patients and to patients with extrapulmonary disease.

DIED A patient who died from any cause during treatment.

FAILED A patient who was initially smear-positive and who remained smear-positive at month 5 or later during treatment.

DEFAULTED A patient whose treatment was interrupted for 2 consecutive months or more.

TRANSFERRED OUT A patient who transferred to another reporting unit and for whom the treatment outcome is not known.

SUCCESSFULLY TREATED A patient who was cured or who completed treatment.

COHORT A group of patients in whom TB has been diagnosed, and who were registered for treatment during a specified time period (e.g. the cohort of new smear-positive cases registered in the calendar year 2004). This group forms the denominator for calculating treatment outcomes. The sum of the above treatment outcomes, plus any cases for whom no outcome is recorded (e.g. "still on treatment" in the European Region) should equal the number of cases registered. Some countries monitor outcomes among cohorts defined by smear and/or culture, and define cure and failure according to the best laboratory evidence available for each patient.

it is newly-classified as DOTS, in which case it would take an additional year to report outcomes from the first cohort of patients treated.

NTPs should ensure high treatment success before expanding case detection. The reason is that a proportion of patients given less than a fully-curative course of treatment remain chronically infectious and continue to spread TB. Thus DOTS programmes must be shown to achieve high cure rates in pilot projects before attempting countrywide coverage.

Stop TB Strategy: implementation and planning (2005–2007)

The information on implementing and planning the Stop TB Strategy presented and analysed in this report reflects activities mostly carried out in the 2005–2006 fiscal year and planned for the 2006–2007 fiscal year (see also **Financing TB control**). For this report, HBC activities and plans were monitored mainly through a questionnaire on Stop TB Strategy implementation sent by WHO to NTP managers of the 22 HBCs in May 2006. The questionnaire[1] was structured around the components of the Stop TB Strategy and included questions on: DOTS expansion and enhancement; laboratory and diagnostic services; human resource development; drug management; monitoring and evaluation system, and impact measurement; collaborative TB/HIV activities; drug-resistant TB; special populations and other high-risk groups; health system strengthening and TB control; Practical Approach to Lung Health (PAL); public–public and public–private mix (PPM) approaches; International Standards for Tuberculosis Care;[2] advocacy, communication and social mobilization (ACSM); community TB care; Patients' Charter for Tuberculosis Care;[3] operational research; Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM); and technical and financial partners.

Other mechanisms were used to clarify or complement responses provided in the questionnaire. These mechanisms included direct discussion with NTP managers, e-mail and telephone communication with NTPs, consultation with international technical agencies, monitoring missions, comprehensive programme reviews, applications to the GFATM, regional NTP managers' meetings, and the annual meeting of the DOTS Expansion, TB/HIV and MDR-TB working groups of the Stop TB Partnership.

Implementation of the Stop TB Strategy in non-HBCs was monitored through analysis of the responses to the Stop TB Strategy questions in the standard data collection form (see **Monitoring progress in TB control**) sent by WHO to all countries. Each component of the Stop TB Strategy was covered in the data collection form but in less detail than the questionnaire.

In developing the country profiles (Annex 1), WHO staff worked closely with NTP managers of the 22 HBCs to:

- assess the main national TB control activities carried out and planned, focusing on improving political commitment, expanding access to DOTS, strengthening laboratory and diagnostic services, ensuring human resource development, strengthening drug management, and improving programme monitoring and supervision;
- summarize progress made by the end of 2006 in implementing, or scaling up, national plans for DOTS expansion;
- identify challenges to reaching the targets for case detection and treatment success;
- determine the status of collaborative TB/HIV activities;
- assess levels of drug resistance and activities planned to address MDR-TB, including mechanisms of drug-resistance surveillance, MDR-TB diagnosis and treatment policies, and the availability of second-line anti-TB drugs;
- identify action plans of the NTP for high-risk groups and special populations;
- describe the contribution of TB control activities to the strengthening of health systems;
- determine the status of additional strategies to expand DOTS, including community participation in TB care, ACSM strategies, and PPM approaches;
- describe the level of operational research carried out and reported;
- review and revise the list of partners supporting DOTS implementation and expansion.

Addressing TB/HIV, MDR-TB and other challenges

Collaborative TB/HIV activities

The WHO policy on collaborative TB/HIV activities[4] emphasizes three areas. First, organizational structures should be put in place to plan and manage collaborative TB/HIV activities. Second, people should be screened for TB when they test positive for HIV and again whenever they attend the health services. If they have active TB they should be treated; if they have latent infection but not active TB they should be given isoniazid preventive therapy (IPT). Third, all TB patients should be given counselling about HIV and encouraged to have an HIV test; if they are HIV-positive they should be offered co-trimoxazole preventive therapy (CPT) and should be assessed for, and started on, antiretroviral therapy (ART) as soon as possible.

In order to assess the extent to which collaborative TB/HIV activities are being implemented, NTP managers were asked if they had a national policy of testing TB

[1] Posted at www.who.int/tb/country/en/

[2] Hopewell PC et al. International standards for tuberculosis care. *Lancet Infectious Diseases*, 2006, 6:710–725.

[3] Posted at www.who.int/tb/publications/2006/istc/en/index.html

[4] *Interim policy on collaborative TB/HIV activities*. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.330; WHO/HTM/HIV/2004.1; available at whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.330. pdf).

patients for HIV in 2005 and to report on the number who were tested for HIV, the number who tested positive, the number who started CPT and ART in 2004 and 2005, as well as the number who are expected to be started on ART in 2006 and 2007. In the 63 countries that account for 98% of the total number of HIV-infected TB cases, NTP managers were also asked for information about their policy on TB/HIV management, and for data on screening for TB and the provision of IPT to people with HIV in 2005. These countries included 58 for which the estimated HIV prevalence in adults aged 15–49 years was greater than 1% in 2004,[1] plus Brazil, India, Indonesia, the Russian Federation and Viet Nam, which are among the 41 countries with the highest numbers of HIV-infected TB patients.[2]

The data were reviewed at WHO regional offices and at headquarters, and an attempt was made to resolve inconsistencies and to obtain missing data in discussions with NTP managers. Because data have now been collected since 2002, time trends in TB/HIV activities are also discussed. Indicators for monitoring and evaluating collaborative TB/HIV activities are available from WHO.[3]

MDR-TB surveillance and control

In 2006, the standard data collection form asked for the following information on MDR-TB surveillance and control:

- whether the management of MDR-TB patients is among the activities of the NTP;
- if practice follows WHO guidelines on the management of drug-resistant TB and, if not, whether the NTP plans to start treating MDR-TB patients in the next two years;
- the number of new and re-treatment patients registered in 2005 who received drug susceptibility testing (DST) at the start of treatment;
- the number of laboratory-confirmed cases of MDR-TB identified among new and re-treatment patients in whom TB was diagnosed in 2005;
- the number of MDR-TB patients expected to be treated in 2006 and 2007;
- treatment outcomes among new, re-treatment and other MDR-TB patients registered in 2002 in GLC-approved and non-GLC approved countries or areas.

In addition to the standard data collection form, the questionnaire on implementation of the Stop TB Strategy sent to HBCs provided further information on plans for drug resistance surveillance (DRS) and MDR-TB diagnosis and treatment, and identified the principal obstacles to implementing these activities.

Besides this information, this report includes data on the prevalence of drug resistance among TB patients collected through the WHO/IUATLD Global Project on Antituberculosis Drug Resistance Surveillance (Global DRS Project), which began in 1994.[4] The project carries out surveys of drug resistance, using established and agreed methods, among patients who present to clinics, hospitals and other health institutions. The fourth report on the global magnitude and trends of drug resistant TB will be published by mid-2007. The profiles of the 22 HBCs (Annex 1) contain estimates of the national prevalence of MDR-TB among both new and previously treated TB patients, based on survey data for those countries participating in the Global DRS Project and for which data are considered reliable. For those countries that have not carried out surveys, or that do not have representative data on new or previously-treated cases, the figures given in the country profiles are estimates based on a regression model described in detail elsewhere.[5]

This report also summarizes the projects approved by the Green Light Committee (GLC) in 2006 for access to quality-assured, second-line anti-TB drugs at reduced prices and independent external monitoring.

Financing TB control (2002–2007)

Financial analysis was introduced into the annual WHO report on global TB control in 2002. The main developments in the 2007 report are that (a) financial data are presented according to the six components of the Stop TB Strategy and/or the (related) cost categories used in the Global Plan, and (b) there is more detailed analysis of how funding needs reported by countries compare with the funding needs set out in the Global Plan. The report has seven objectives:

- for each HBC, and for all HBCs combined, to present and assess total NTP budgets and expenditures for the period 2002–2007, with breakdowns by funding source and line item;
- for each HBC and for all HBCs combined, to present and assess the total cost of TB control to government health services[6] for the period 2002–2007, with breakdowns by funding source and line item;
- for each HBC, to estimate and compare per patient costs, budgets and available funding for the period 2002–2007 and per patient expenditures for 2002–2005;
- for each HBC, to assess whether increased spending on TB control is resulting in an increase in the number of cases detected and treated in DOTS programmes;

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1 HIV prevalence estimates for 2004 (unpublished data). Geneva, UNAIDS.

2 Questionnaires are available at www.who.int/tb/country/en/

3 *A guide to monitoring and evaluation for collaborative TB/HIV activities*. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.342 and WHO/HIV/2004.09; available at whqlibdoc.who.int/hq/2004/WHO_ HTM_TB_2004.342.pdf).

4 The WHO/IUATLD Global Project on Anti-tuberculosis Drug Resistance Surveillance. *Anti-tuberculosis drug resistance in the world. Third global report*. Geneva, World Health Organization, 2003 (WHO/HTM/TB/2004.343; more information about the project can be found at: www.who.int/tb/dots/dotsplus/surveillance/en/index.html).

5 Zignol M et al. Global incidence of multidrug-resistant tuberculosis. *Journal of Infectious Diseases*, 2006, 194:479–485.

6 i.e. including costs not reflected in NTP budget data.

- to assess the contribution of the GFATM to funding for TB control;
- for countries other than the HBCs, to quantify NTP budgets and total TB control costs in 2007, with breakdowns by funding source and line item;
- for the HBCs and other countries, to compare funding requirements reported by countries with the funding needs for 2006 and 2007 set out in the Global Plan.

Data collection

We collected data from five main sources: NTPs, the WHO-CHOICE team,[1] GFATM proposals and databases, previous WHO reports in this series, and epidemiological and financial analyses carried out for the Global Plan.[2] In 2006, data were collected directly from countries using a two-page questionnaire included in the standard WHO data collection form. NTP managers were asked to complete three tables. The first two tables required a summary of the NTP budget for fiscal years 2006 and 2007, in US$, by line item and source of funding (including a column for funding gaps). The third table requested NTP expenditure data for 2005, by line item and source of funding. The form also requested information about infrastructure dedicated to TB control and the ways in which general health infrastructure is used for TB control (e.g. the number of dedicated TB beds available, the number of outpatient visits that patients need to make to a health facility during treatment and the average length of stay when patients are admitted to hospital). We also asked for an estimate of the number of patients who would be treated in 2006 and 2007, for (a) smear-positive and (b) smear-negative and extrapulmonary cases combined.

Line items for the budget tables were revised from those used in previous years, to bring reporting of financial data in line with the Stop TB Strategy and to allow for comparisons with the cost categories used in the Global Plan. A total of 10 line items were defined: first-line drugs; dedicated NTP staff; routine programme management and supervision activities; laboratory supplies and equipment; second-line drugs for MDR-TB; management of MDR-TB (budget excluding second-line drugs); collaborative TB/HIV activities; ACSM, and community-based care; operational research; and all other budget lines for TB (e.g. technical assistance). The relationship of these items to the Stop TB Strategy and the Global Plan and the categories used for presentation of financial analyses in this report are shown in Table 6.

Data entry and analysis

High-burden countries

Data entry and analysis focused on the 22 HBCs. We created a standardized Microsoft Excel workbook, with one worksheet for each country. Additional worksheets were included for summary analyses and for the data required as inputs to the country-specific analyses (e.g. notification data, unit costs for bed-days and outpatient clinic visits). For each country worksheet, 10 tables and related figures were created:

- NTP budget line items in 2006 and 2007, according to the 10 categories used in the 2006 round of data collection;
- NTP budget by line item for each year 2002–2007. Line items were grouped to allow for comparisons with the Global Plan and the Stop TB Strategy. This grouping, both for the budget categories used in 2006 and for those used in 2002–2005, is explained in Table 6. This was supplemented by an additional table for the NTP budget 2002–2005, according to the detailed line items used in 2002–2005;
- NTP budget by source of funding for each year 2002–2007, with the funding sources defined according to the 2006 data collection form, i.e. government (excluding loans), loans, GFATM, grants (excluding GFATM) and budget gap;
- NTP expenditures by source of funding for 2002–2005, with funding sources as defined for NTP budgets;
- NTP expenditures by line item for 2002–2005, with line items defined according to the budget categories used for reporting in the 2005 round of data collection, i.e. first-line drugs, second-line drugs, dedicated NTP staff, initiatives to increase case detection and cure rates, collaborative TB/HIV activities, buildings/equipment/vehicles, and other. These categories were retained for expenditure data to allow direct comparison with budget data reported for 2005;
- total TB control costs by funding source for each year 2002–2007, with funding sources as defined for NTP budgets;
- total TB control costs by line item for each year 2002–2007, with line items defined as NTP budget items, hospitalization and clinic visits;
- per patient costs, NTP budget, available funding, expenditures and budget for first-line drugs;
- comparison of total costs based on the country report, with total costs implied by the Global Plan;
- comparison of NTP budget, available funding and expenditure for 2003–2005 by line item.[3]

Budget data for 2006 and 2007 were taken from the 2006 data collection form. Budget data for 2005 were taken from the 2005 data collection form. Budget data for 2002–2004 were taken from the 2005 annual report. Expenditure data for 2002, 2003, 2004 and 2005 were based on the 2003, 2004, 2005 and 2006 data collection forms, respectively.

[1] The WHO-CHOICE (CHOosing Interventions that are Cost-Effective) team conducts work on the costs and effects of a wide range of health interventions.

[2] *The Global Plan to Stop TB, 2006–2015: methods used to assess costs, funding and funding gaps*. Geneva, Stop TB Partnership and World Health Organization, 2006 (WHO/HTM/STB/2006.38).

[3] Expenditure data are available for a larger set of countries in 2003 compared with 2002. For this reason, comparisons are with 2003.

TABLE 6

Categories used for presentation of financial analyses in this report and their relationship to the Stop TB Strategy, the Global Plan, budget lines used on the WHO data collection form and budget lines used in previous WHO reports

CATEGORIES USED FOR FINANCIAL ANALYSES IN THIS REPORT THAT COVER THE PERIOD 2002–2007	STOP TB STRATEGY	GLOBAL PLAN	BUDGET LINES IN 2006 DATA COLLECTION FORM	BUDGET LINES PRIOR TO 2006
DOTS	Component 1	DOTS	First-line drugs; NTP staff; routine programme management and supervision activities; laboratory supplies and equipment	First-line drugs; NTP staff; buildings, vehicles, equipment; all other budget lines for TB
MDR-TB	Component 2	MDR-TB/ DOTS-Plus	Second-line drugs for MDR-TB; management of MDR-TB (excluding second-line drugs)	Second-line drugs
TB/HIV		TB/HIV	Collaborative TB/HIV activities	Collaborative TB/HIV activities
New approaches: PPM/PAL/ community TB care/ACSM	Components 3–5	New approaches to DOTS	PPM and PAL; ACSM and community TB care	New initiatives to increase case detection and cure rates
		ACSM		
Operational research	Component 6	Not included as specific categories	Operational research	Not included as specific category
Other	Not applicable		All other budget lines for TB (e.g. technical assistance)	"Other" category existed; for this report it is included under DOTS

Total TB control costs were estimated by adding costs for hospitalization and outpatient clinic visits to either NTP expenditures (for 2002–2005) or NTP budgets (for 2006–2007). Expenditures were used in preference to budgets for 2002–2005 because they reflect actual costs, whereas budgets can be higher than actual expenditures (for example, when large budgetary funding gaps exist or when the NTP does not spend all the available funding). When expenditures are known for 2006 and 2007, they will be used instead of budget data to calculate, retrospectively, the total cost of TB control in these years. For some HBCs, expenditures were not available for 2002–2005. When this was the case, we generally estimated expenditures based on available funding, which was calculated as the total budget minus the funding gap. The exception was South Africa, which reported budget and expenditure data for the first time in 2006. In previous annual reports, costs in South Africa were based on costing studies undertaken in the mid to late 1990s. Given the availability of new information from the 2006 round of data collection, we revised previous cost estimates for 2002–2004 by assuming that per patient costs in these years would be as for 2006. Total costs were then estimated by multiplying total notifications in each year by the estimated cost per patient treated. This produces lower estimates of total costs for South Africa, and explains differences in the total costs figures previously reported for the 22 HBCs during the period 2002–2006.

The total cost of outpatient clinic visits was estimated in two steps. First, the unit cost (in US$)[1] of a visit was multiplied by the average number of visits required per patient (estimated on the WHO data collection form), to give the cost per patient treated. This was done separately for (a) new smear-positive cases and (b) new smear-negative and extrapulmonary cases. Second, we multiplied the cost per patient treated by the number of patients notified (for 2002–2005) or the number of patients whom the NTP expects to treat (for 2006–2007). The total costs for the two categories of patient were then summed. The cost of hospitalization was generally calculated in the same way, replacing the unit cost of a clinic visit with the unit cost of a bed-day. The procedure differed for eight countries that have dedicated TB beds, and where the total cost of these beds is higher than when the total cost is estimated by multiplying bed-days per patient by the number of patients treated (this applied to Bangladesh, Brazil, Cambodia, India, Myanmar, the Russian Federation, UR Tanzania and Zimbabwe). We assumed that all clinic visits and hospitalization are funded by the government, because staff and facility infrastructure are the major inputs included in the unit cost estimates, and these are typically not funded by donors.

Per patient costs, budgets, available funding and expenditures were calculated by dividing the relevant total by the number of cases notified (for 2002–2005) and the number of patients whom the NTP expects to treat (for 2006–2007). Since the total costs of TB control for 2002–2005 were based on expenditure data, it is possible for the total TB control cost per patient treated to be less than the NTP budget per patient treated when the funding gap

[1] Average costs in the WHO-CHOICE database are reported in local currency units. These were converted into US$ using exchange rate data provided in the IMF *International financial statistics yearbook*. Washington, DC, International Monetary Fund, 2003.

is large or there is a significant budgetary under-spend. In addition, for 2002–2005, expenditures per patient were sometimes higher than the available funding per patient. This can occur when the NTP budget funding gap is reduced after the reporting of budget data to WHO (since available funding is estimated as the total budget minus the funding gap). To try to eliminate this problem, the data collection form has allowed countries to update budget data reported in the previous round of data collection since 2005 (for example in the 2005 round of data collection, countries were able to update 2005 budget data originally reported in 2004; in the 2006 round of data collection, countries were able to update 2006 budget data originally reported in 2005).

Costs based on country reports reflect actual country plans for TB control. To address the question of whether these costs are in line with the Global Plan, we converted the regional costs that appear in the Global Plan into estimates for individual countries. While these costs should be seen as approximations only, they can be used to identify important similarities and differences between country reports and the Global Plan. Differences may occur if the intervention coverage and rates of scale-up (e.g. number of TB patients to be treated or number of HIV-positive TB patients to be enrolled on ART) planned by countries in 2006 and 2007 are more or less ambitious than the projections included in the Global Plan, and/or if country-specific budget development is based on input prices that are more or less than the average regional prices used in the Global Plan. A further reason for discrepancies is that, while the Global Plan includes the full cost of collaborative TB/HIV activities, the budget for these activities that is reported by NTPs includes only the budget managed by the NTP, and not the budget for such activities that is managed by the national AIDS programme. Table 7 summarizes the methods used to convert regional costs as they appear in the Global Plan into estimates for individual countries.

All budget and expenditure data are reported in nominal prices (i.e. not adjusted for inflation) rather than constant prices (i.e. all prices adjusted to a common year) for two reasons. First, this means that values given for individual countries in *Global tuberculosis control* reports for the years 2002–2006 do not have to be adjusted, which makes it easier for country staff to review the data for previous years. Second, the adjustment makes only a small difference to the numbers reported (about 11% to 2002 values for total costs and less for other years).

Once the data were entered, any queries were discussed with NTP staff and the appropriate WHO regional and country office, and a final set of charts was produced. Six of these charts appear in the profiles for each country at Annex 1: NTP budget by line item 2002–2007, with line items as defined in the first column of Table 6; NTP budget line items in 2007, according to the line items used in the 2006 round of data collection; NTP budget by funding source 2002–2007; total TB control costs by line item 2002–2007; per patient costs, budgets, available funding, expenditures and budget for first-line drugs 2002–2007; and costs according to country reports compared with costs implied by the Global Plan for 2006 and 2007.[1] In some instances, the review process led to revisions to data included in previous annual reports. For this reason, figures sometimes differ from those published in the 2002–2006 reports.

To assess whether increased spending on TB control has resulted in an increase in the number of cases detected and treated in DOTS programmes, we compared the change in total NTP expenditures between 2003 and 2005 with the change between 2003 and 2005 in (a) the total number of TB cases treated in DOTS programmes and (b) the total number of new smear-positive cases treated in DOTS programmes. This was done for all HBCs for which the necessary data existed (not all countries have reported expenditure data for both years).

Finally, we compared the total costs of TB control with total government health expenditure.[2] We also examined the association between GNI (gross national income) per capita in 2005 and government contributions to total NTP budgets and TB control costs. Data on GNI per capita were taken from *World development indicators 2005*.[3]

Other countries

For countries other than the HBCs, we used the data provided on the 2006 data collection form to assess NTP budgets by region in 2007, and compared these data with the budgets reported by the HBCs. Only countries that submitted complete data of sufficient quality (e.g. data whose subtotals and totals were consistent by both line item and funding source) were used.

We also made estimates of the costs implied by the Global Plan for the 172 countries in the regions covered by the plan, as described above for the 22 HBCs. We then aggregated these values for each WHO region for the subset of countries that (a) provided a complete budget report to WHO and (b) were included in the Global Plan. The total number of countries meeting both criteria was 62. We then compared these aggregated values to costs according to country reports.

GFATM contribution to TB control

We evaluated GFATM funding for both HBCs and other countries, as announced after the first six rounds of funding. We assessed total approved funding at the end of 2006, disbursements to the end of 2006, the time taken between approval of a proposal and the signature of grant agreements, and the time taken between the signing of the grant agreement and the first disbursement of funds.

[1] A full set of charts and data is available upon request to tbdocs@who.int

[2] See www.who.int/nha/country/en

[3] Accessed in December 2006: devdata.worldbank.org/data-query

TABLE 7

Methods used to allocate regional costs in the Global Plan to individual countries

COUNTRY	NUMBERS OF PATIENTS			COSTS					
	NUMBER OF SS+ AND SS–/EP PATIENTS TREATED IN DOTS PROGRAMMES	NUMBER OF MDR-TB PATIENTS TREATED IN "DOTS-PLUS" PROGRAMMES	NUMBER OF HIV+ TB PATIENTS ENROLLED ON ART	NTP BUDGET FOR DOTS, EXCLUDING NEW APPROACHES	NTP BUDGET FOR NEW APPROACHES TO DOTS IMPLEMENTATION	BUDGET FOR ACSM	BUDGET FOR ART FOR HIV+ TB PATIENTS, AND OTHER TB/HIV COLLABORATIVE ACTIVITIES	NTP BUDGET FOR MDR-TB TREATMENT	COSTS ASSOCIATED WITH UTILIZATION OF GENERAL HEALTH SERVICES, FINANCED FROM GENERAL HEALTH FACILITY BUDGETS
Afghanistan Bangladesh Cambodia China India Indonesia Myanmar Pakistan Philippines Thailand Viet Nam	Global Plan regional numbers allocated to each country according to its share of the regional burden of TB (in 2004).	Global Plan regional numbers allocated to each country according to its estimated share of the regional burden of MDR-TB cases in 2003 (source: DOTS-Plus Working Group).	Estimates were made for each country as a joint effort by the Stop TB Partnership and UNAIDS for the Global Plan. Country-specific numbers were therefore already available and no allocation process was required.	The NTP budget per patient in each country in 2005 was used in the Global Plan to estimate a budget per patient for the region as a whole, with each country weighted according to its share of regional cases. To return to country-specific estimates, we used the NTP budget per patient in each country that was used in the Global Plan. This is the NTP budget reported in the 2005 WHO TB control report, excluding second-line drugs and collaborative TB/HIV activities. The NTP budget for each country that underpinned the Global Plan regional calculations was then multiplied by the number of cases to be treated (estimated as explained in column 2).	Global Plan cost estimates were first made for a standard population of 500 000, or in the case of culture and DST laboratories for a population of 5 million, based on regional unit prices. These unit costs were then multiplied by a factor according to the size of the regional population to be covered (e.g. if the population to be covered was 100 million, the unit cost was multiplied by 200, or by 20 in the case of culture and DST laboratories). To estimate costs for each country, Global Plan costs for each region were allocated to each country according to its share of the regional population.		The number of TB/HIV patients on ART was multiplied by the unit cost of providing ART, estimated by UNAIDS for each country as part of the development of the Global Plan. For other activities, the number of patients was allocated to a country according to its share of the regional TB/HIV burden and then multiplied by the country-specific unit cost used in the Global Plan.	Calculated as the number of MDR-TB cases to be treated multiplied by a country-specific unit cost. Country-specific unit costs estimated by adjusting the regional cost used in the Global Plan according to GNI per capita (except for the cost of drugs, which were assumed to be the same in all countries).	Calculated on a per patient basis for each country according to the inputs reported in the 2006 WHO data collection form. Unit costs for hospitalization and outpatient visits are WHO country-specific estimates as opposed to the DCPP regional estimates used in the Global Plan. Costs for diagnostic tests among TB suspects were included in the Global Plan, but were not included in the country-specific estimates because there are no comparative data from countries (the number of such tests is not requested on the WHO data collection form).
Brazil Russian Federation	Global Plan regional numbers allocated to each country according to its share of the regional burden of TB (in 2004), then adjusted according to target level of DOTS population coverage set out in the Global Plan.								
DR Congo Ethiopia Kenya Mozambique Nigeria South Africa Uganda UR Tanzania Zimbabwe	Global Plan regional numbers allocated to each country according to its share of regional cases treated under DOTS (in 2004).								

ART indicates antiretroviral therapy; DOTS-Plus, the term used for the management of MDR-TB patients according to international guidelines at the time of the development of the Global Plan; DST, drug susceptibility testing; HIV+, HIV-positive; NTP, national tuberculosis control programme; ss+, sputum smear-positive; ss–, sputum smear-negative; EP, extrapulmonary.

We also assessed how the total value of grants awarded for TB control has evolved between rounds 1 and 6, and the approval rate. The approval rate was calculated as the number of proposals considered by the GFATM Technical Review Panel in each round, divided by the number of proposals approved in each round (including proposals approved after appeal). This approval rate was compared with applications for malaria and HIV/AIDS.